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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,171	01/04/2007	Petr Joseph Ayrc	CU-4989 EJC	5161
26530	7590	10/29/2007	EXAMINER	
LADAS & PARRY LLP			LAVERT, NICOLE F	
224 SOUTH MICHIGAN AVENUE			ART UNIT	
SUITE 1600			PAPER NUMBER	
CHICAGO, IL 60604			4123	
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			10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/588,171

Applicant(s)

AYRE ET AL.

Examiner

Nicole F. LaVert

Art Unit

4123

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 August 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: a) the individual components, "medical assist device" and "implanted medical device" are both designated by the reference number "2," (pp 4, lines 9 & 17), b) The word "minimised," is spelled wrong and should be changed to "minimized," (pp 9, lines 17-18). Appropriate correction is required.
2. The use of the trademarks Dacron™ [(pp 5, line 11) & (pp 8, line 8)], Nusal™ [(pp 7, lines 1 & 18) & (pp 8, lines 18 & 21)], Kevlar™ (pp 7, line 23), and Velcro™ (pp 11. lines 13, 18, 20 & 22) has been noted in this application. The trademarks should be capitalized wherever they appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a) because they fail to show a "thin region 20," as described in the specification (pp 8, lines 11). Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the

appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because in respect to Figure 5, reference numbers "33" and "35" seem to be pointing to the same component. No distinction is made between the two different components according to the figure. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not

accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

Claims 6 & 7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 6 & 7 are directed to nonstatutory subject matter, due to the claims reciting a part of the human body.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claims 1-2, & 4-5** are rejected under 35 U.S.C. 102(b) as being anticipated by Jarvik et al. (US 5,904,646)

For **claim 1**, Jarvik et al. discloses a percutaneous lead assembly for supplying electrical signals to a medical device implanted within a body of a patient (col 2, lines 6-11), said lead assembly comprising a flexible elongate member having a first portion adapted to remain external to the body of a patient [(col 2, lines 21-26) & (Figure 2, 57)], said first portion having a first diameter (Figure 2, 57); and a second portion joined to said first portion [(col 2, lines 21-26) & (Figure 2, 33)] and adapted to extend through a hole in a skin layer of the body of the patient (Figure 6, 7), and wherein said second portion having a second diameter (Figure 2, 33) which is substantially smaller than said first diameter (Figure 6).

In reference to **claim 2**, Jarvik et al. discloses, the percutaneous lead assembly as claimed in claim 1 (col 2, lines 6-11), wherein said first portion includes a shielding layer [(col 4, lines 41-44) & (Figure 4A, 74)].

In reference to **claim 4**, Jarvik et al. discloses, the percutaneous lead assembly as claimed in claim 1 (col 2, lines 6-11), wherein said first portion (Figure 2, 57) and said second portion (Figure 2, 33) are joined by connectors [(col 3, lines 24-49) & (Figure 5, 30 & 60)].

In reference to **claim 5**, Jarvik et al. discloses, the percutaneous lead assembly as claimed in claim 1 (col 2, lines 6-11), wherein said percutaneous lead assembly includes a lead restraint [(col 2, lines 27-34); (col 3, lines 1-8) & (Figure 1, 2)].

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claim 3** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jarvik et al. (US 5,904,646) in view of Shonk et al. (US 4,699,157).

Jarvik et al. shows all features of the instantly claimed invention as discussed above.

Jarvik et al. fails to teach a second portion covered by a textured surface.

Shonk et al. teaches an inner tube that has a textured surface with a resultant mating texture of a solid polymer (col 7, lines 1-7).

It would have been obvious to one of ordinary skill in the lead assembly art to have modified Jarvik et al. with the use of an inner tube that has a textured surface as taught by Shonk et al. as it is known in the art.

9. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jarvik et al. (US 5,904,646) in view of Hampton et al. (US 2003/0028148 A1).

Jarvik et al. shows all features of the instantly claimed invention as discussed above.

Jarvik et al. fails to disclose an excess length of lead releasably secured near to a hole in a patient's skin.

Hampton et al. teaches tubing of a predetermined distance releasably secured near to a hole in a patient's body, which may be adjusted and or replaced in order to avoid any discomfort at the body entry site ([0030]-[0031]).

It would have been obvious to one of ordinary skill in the lead assembly art to have modified Jarvik et al. with the use of an excess length of lead releasably secured to the hole in the patient's body as taught by Hampton et al., in order to prevent movement of the tubing from reaching the body entry site or to be able to adjust or replace the tubing without disturbing or damaging the skin at the entry site.

10. **Claim 7** is rejected under 35 U.S.C. 103(a) as being unpatentable over Jarvik et al. (US 5,904,646) in view of Imran et al. (US 5,449,381).

Jarvik et al. shows all features of the instantly claimed invention as discussed above.

Jarvik et al. fails to teach a flexible, elongated member that extends through a hole in a skin layer of the body.

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Imran et al. teaches a catheter, including a flexible elongated, tubular member, which is placed beneath the skin and extends to the heart [(col 2, lines 37-42) & (col 4, lines 52-55)].

It would have been obvious to one of ordinary skill in the lead assembly art to have modified Jarvik et al. with the a flexible elongated, tubular member, which is placed beneath the skin in order to provide a flexible, elongated member that extends through a hole in a skin layer of the body.

Conclusion

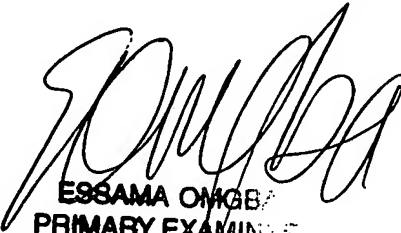
11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole F. LaVert whose telephone number is 571-270-5040. The examiner can normally be reached on M-F 7:30-5:00p.m. (Alt. Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

N.F.L.



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PRIMARY EXAMINER